DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#14

APR 30 1991

Re: Ganite
Docket No. 91E-0124

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,529,593, filed by the Sloan-Kettering Institute for Cancer Research, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Ganite, the human drug product claimed by the patent.

The total length of the review period for Ganite is 6,279 days. Of this time, 5,610 days occurred during the testing phase and 669 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 10, 1973.

   FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was November 10, 1973.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: March 20, 1989.

   The applicant claims March 17, 1989, as the date the new drug application (NDA 19-961) was filed. However, FDA records indicate that the NDA was received at FDA on March 20, 1989.

3. The date the application was approved: January 17, 1991.

   FDA has verified the applicant's claim that NDA 19-961 was approved on January 17, 1991.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: John P. White
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